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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,740	12/27/2001	Bradley J. Enegren	PF00434 US	1376
23608	7590	08/27/2003		EXAMINER
MEDTRONIC MINIMED INC. 18000 DEVONSHIRE STREET NORTHRIDGE, CA 91325-1219				NASSER, ROBERT L
			ART UNIT	PAPER NUMBER
			3736	
DATE MAILED: 08/27/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/034,740	ENEGREN ET AL. <i>W</i>
	Examiner	Art Unit
	Robert L. Nasser	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 12-20 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-11 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to an implantable sensing device, classified in class 600, subclass 345.
- II. Claims 12-19, drawn to a method for cleaning a sensing device, classified in class 128, subclass 898.
- III20. Claim 20, drawn to a system for cleaning a sensor, classified in class 128, subclass 897.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus could be used to practice a materially different method, such as a method of sensing a body fluid parameter.

Inventions I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as measuring a blood constituent. See MPEP § 806.05(d).

Inventions II and III are related and would be examined together, if elected. The examiner split them up for this write up to explain that both the method claims 12-19 and the system 20 were distinct from the sensor claims 1-11.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Paul Kovelman on August 18, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-1. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-20 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the one way valve of claim 5 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction

of the following is required: There is no disclosure of the subject matter of claim 5, i.e. the one way valve.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 8 recites that the connector fitting is affixed internally to the patient. The patient is non-statutory subject matter and cannot be positively recited. Accordingly, this claim recites non-statutory subject matter. Applicant should amend the claim to recite that the fitting is affixable internally, or use similar intended use language.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6, 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Margules. Margules includes an implantable sensor assembly 10, having a sensor tip 12, housing a sensor 24 and 34. The device further includes a flush sleeve housing

channel 16 for providing fluid to the tip flush the outer surface of sensor 34 of any impurities. Margules further includes a connector fitting 40 to which the sensor is plugged. The flush sleeve further is tight fit to the sensing apparatus. Fluid conduit 16 is further located at the proximal end of the device. With respect to claims 9 and 10, applicant has not recited a fluid source. As such, any fluid could be used in lumen 16 to flush sensor 34 and 24. With respect to claim 3, the examiner notes that connector 46 divides the fluid line into two sections a catheter part and a supply part. Hence it is a septum and it is piercable by a syringe.

Claims 1, 2, and 4-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Pfeiffer. Pfeiffer shows a device including a catheter having a sensor 7 with a sensor tip 4a and a flush sleeve housing channels 2 which carries fluid to tip 4a to clean the tip. The flush sleeve is tight fit to the sensing device. In addition, it runs from the proximal to the distal end of the sensor. There is also a connector 20 or 21, as recited in the claims and a protective sleeve 5 and 6. Again, any fluid could be used, as discussed above. In addition, there is a one way valve 13.

Claims 1, 4, 6, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Koning et al. Koning shows a catheter having a sensor tip that is for direct contact with body fluids, a flush sleeve 14 which carries calibration fluid (which is also a flushing fluid) to the sensor tip, where the sensing tip is in a tight fit relationship to the flush sleeve.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Margules in view of Gough et al. Margules connects the sensor 24 to a monitoring device via a cable. Gough et al teaches what is well known in the art, that wirelessly transmitting signals from a device inside the body to the monitor outside the body is an alternate way of communicating patient data to a monitor. Hence, it would have been obvious to modify Margules to use a wireless transmitter, as it is merely the substitution of one known equivalent in the art for another.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Graham shows another device with similar structure to applicant's invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

*Robert L. Nasser*  
Robert L. Nasser  
Primary Examiner  
Art Unit 3736

RLN  
August 24, 2003

ROBERT L. NASSER  
PRIMARY EXAMINER

Application/Control Number: 10/034,740  
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